Cross-sectional Study Evaluating the Effectiveness of Venetoclax Risk-Minimisation Measures Among Haematologists in Europe

First published: 14/07/2023

Last updated: 25/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104738

EU PAS number

EUPAS104737

Study ID

104738

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Poland
- [ ] Spain
- [ ] United Kingdom

Study description

This study will be a cross-sectional survey to evaluate the receipt and use of the Direct Healthcare Professional Communication (DHPC), including knowledge among participating haematologists regarding Tumour Lysis Syndrome (TLS) assessment and adherence to the TLS risk-minimisation measures following availability of the venetoclax revised Summary of Product Characteristics (SmPC) and dissemination of DHPC in Europe. Haematologists from at least 5 European countries will be recruited and asked to complete a one-time self-administered structured questionnaire.

Study status

Ongoing

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Daniel Wolin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/08/2021

Study start date

Actual: 01/11/2023

Date of final study report

Planned: 31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

P22907-protocol-abstract_redacted.pdf(124.23 KB)

P22-907_Protocol_v1.1_Redacted.pdf(766.17 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

P22-907

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To assess haematologists' knowledge of the following:

- TLS as a risk of venetoclax treatment for CLL
- Signs/symptoms of TLS
- The importance of strict adherence to venetoclax dose titration and TLS risk-minimisation measures as outlined in the SmPC for all patients.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

VENCLYXTO

Study drug International non-proprietary name (INN) or common name

VENETOCLAX

Anatomical Therapeutic Chemical (ATC) code

(L01XX52) venetoclax

venetoclax

Medical condition to be studied

Chronic lymphocytic leukaemia

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

200

Study design details

Data analysis plan

The analyses will be descriptive in nature and will include distributions of the responses to all of the individual questions and, if appropriate, summary measures across logical groupings of questions. Descriptive tables will be generated for the physicians overall and stratified by country and other identified variables of interest. Analysis tables will include the frequency and

percentage of physicians who select each response to each individual question.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Hematologists will be recruited from an online panel of physicians available for research and will provide data via self-report web-based questionnaires.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No